HEMODIALYSIS EQUIPMENT AND PRACTICES IN MASSACHUSETTS

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TABLE OF CONTENTS

I. INTRODUCTION

A. Background

In the past fifteen years there have been uprecedented developments in dialyzer technology and related instrumentation for the treatment of end stage renal disease (ERSD). Improvements in dialysis therapy continue to make treatment briefer and more effective. For tens of thousands of patients in this country with chronic renal failure, hemodialysis provides rehabilitation and a dramatic increase in life expectancy.

The goal of dialysis is to replace the normal kidney function of urine production, which regulates the body's levels of urea and other end products of protein metabolism of water and of acid and base. Dialysis treatment alleviates certain pathological conditions collectively referred to as uremia, that are engendered by loss of these normal kidney functions. Other kidney functions, such as secretion, of hormones are not replaceable by dialysis alone.

B. System Description

The process of hemodialysis, based on the principles of diffusion and filtration, and simple in concept and design, replaces the aforementioned kidney functions with minimal harm to the blood. It is accomplished by pumping blood, shunted from an artery, through narrow channels separated by semi-permeable membranes from a specially prepared second fluid, the dialysate, and returning the blood to a vein. A schematic diagram of a typical unit is illustrated in Figure 1.

In a common hemodialyzer configuration, the narrow channels are formed by thousands of biocompatible, cellulosic hollow fiber membranes stretched between the bases of a plastic cylinder approximately one foot long and two inches in diameter (See Figure 2).

The membranes' pores allow passage of water and other small molecules, while retaining proteins, red cells and other larger blood components. The dialysate, a pre-mixed solution in water, flows within the cylinder in the spaces between the tubes.

Membrane-permeable species transfer between the blood and the dialysate. Transfer of solutes such as urea or bicarbonate is driven primarily by the difference between the solute's concentrations in the blood and dialysate. The transfer of water is driven by osmotic and hydrostatic pressures.

With patient blood in a given state and fed at a certain rate, the pressure, composition and feed rate of dialysate constitute the primary variables at the disposal of the operator to control the diffusion and filtration rates essential to dialysis. Ideally, the pressure and composition of the dialysate feed should be tailored on an ad hoc basis to the blood-cleaning needs of the individual patient. In practice, however, dialysate is prepared by diluting with water a pre-purchased, pre-mixed standard dialysate concentrate. Preparation of dialysate is a vital procedural step, upon which close attention must be focused even when pre-mixed concentrate is employed, because of the necessity to purify the water with which the concentrate is diluted.

In addition to restoring the blood's levels of urea, water and other chemicals to within tolerable limits, the hemodialysis system must maintain the blood at physiological temperature and pressure, free of gas bubbles, untraumatized and sterile.

C. Problems with Hemodialysis

The problems associated with hemodialysis can be divided into four major categories:

- physiological disorders of the uremic patient that remain unremediated by dialysis

- undesirable side effects of dialysis
- results of system failures
- results of operator oversights

The first two problem groups arise from physiological conditions peculiar to patients which make them either unreceptive to dialysis treatment or hypersensitive to the dialysis unit. The third set of problems includes equipment malfunctions due either to faulty or improperly designed equipment, or to poor maintenance practices. The final group or problems may be caused by the operator's poor monitoring practices, or by insufficient provision of operating information or training by the manufacturer.

II. OBJECTIVE

The objective of this study was to assess the hemodialysis services provided by twenty-two hospital-based and free-standing treatment centers in Massachusetts, (see table 1) with respect to operational features that may result in significant patient problems. The potential for problems in the latter two of the four above categories were identifed.

III. SUMMARY OF INAPPROPRIATE RESPONSE

The survey was comprised of questions regarding four major elements of dialysis operation: the water treatment system, dialysate delivery system, extracorporeal blood circuit and the dialyzer proper. A copy of the survey questionnaire is included in Appendix B. The questions largely explore consistency of clinical practice with the "American National Standard for Hemodialysis System," recommended by the Renal Disease and Detoxification Committee of the Association for the Advancement of Medical Instrumentation, and approved in May 1982 by the American National Standards Institute, Inc.

The survey questionnaire was designed to identify potential problems due to:

- operational aspects of the equipment including monitoring and alarm systems
- poor system design or system malfunctions
- insufficient information, training or education by the manufacturer
- miscellaneous other sources.

Answers were obtained in interviews with operating personnel, as well as by inspection of equipment and manufacturers' equipment specifications and operating instructions. The following is a summary of responses that suggested to the project team's consulting clinician and biomedical engineer the potential for significant problems. No attempt was made to deduce cause-and-effect relationships between potentially hazardous situations and reported adverse patient response.

A. Water Treatment

The water that dilutes the dialysate concentrate must be deionized (See Table 2 for recommended composition). Tap water typically undergoes reverse osmosis and/or some other filtration, ion exchange or adsorption process to remove electrolytes and other solutes and contaminants. The water and process equipment must also be disinfected. Ion exchange and adsorption columns undergo exhaustion and must therefore be periodically regnerated or discarded. The performance of the water treatment system is monitored, both through automated analyzers, preferrably with alarms, as well as periodic sampling by the operator.

1. Operations, Monitoring, Alarms

The water treatment systems must be properly disinfected by the operators. Furthermore, the proper functioning of the systems must be monitored, both by automatic controls affixed to the instrumentation, and periodic checks by the operators. This section reports the incidence of reponses to survey questions which indicated advserse circumstances regarding disinfection, the existence, functioning and maintence of alarms, or operator practice with respect to the monitoring of treated water. Frequencies of adverse reponses appear in this section and in table 3.

Disinfection is necessary to prevent bacterial growth. In only one of the twenty-two facilities inspected was it found that the water treatment equipment was not disinfected. However, in five, disinfection was not carried out at the time of regeneration or reconstruction of a system component, raising the potential for bacterial growth. Furthermore, in four, piping or another part of the water treatment system was not disinfected.

Adverse situations regarding the state of warning and alarm systems were also observed. In four facilities, the alarm on the conductivity detector which indicates excess electrolyte that could promote excessive water loss from the blood was not tested. In ten, the warning and alarm systems were not calibrated periodically.

In several facilities treated water was not thoroughly monitored. In one, the water's ph was not monitored. Such monitoring is warranted because improper ph could trigger precipitation of carbonate in the dialysate and problems with the heparin employed to prevent clotting of the blood.

The treated water was not analyzed for chlorine in three facilities or for chloramine in two. The recommended maximum level of 0.54 mg/l chlorine was not enforced at one facility, while the recommended level of 0.01 mg/l aluminum was not followed at three.

Total electrolyte concentration regulates the osmotic pressure of the water, and hence of the dialysate. This, in turn, affects the rate of water removal from the patient's blood. Hence, the water is deionized, and the mixed dialysate electrolyte concentration is determined by that of the original concentrate. In several facilities, the efficiency of the deionization system was judged to be inadequately monitored.

In two facilities, the effluent from the deionization system was not continuously monitored to check that the water's resistivity exceeded one megohm-cm. Lower values indicate higher electrolyte concentrations, which may cause excess water transfer from blood to dialysate. In four facilities, the performance of the reverse osmosis system (one means of deionization) was not continuously monitored for leakage of electrolyte into the purified water. In five, the conductivities of the source and effluent water processed through reverse osmosis systems were not continuously monitored.

2. Malfunctions or Design Errors

This section describes adverse survey responses with respect to the design, such as provision of adequate safety features, alarms, or proper functioning, of the water treatment equipment (see also table 4).

In five of the twenty-two facilities, there was no alarm on the conductivity detector which monitors electrolyte concentration in the effluent from the water treatment system. In two systems with alarms there were alarm failures. In one, the alarm light did not flash and, in the other, the meter itself was found to be broken. In five facilities, there were no shutdown, bypass, or other alternative paths when monitored variables exceeded tolerable limits. In seven, the intensity audible alarms was not at least 70 decibles at 3 meters, and/or the alarms were not sustained

without the possibility for interruption for more than 180 seconds. A main electrical failure was not indicated by an audible alarm in ten facilities.

In three facilities, electrical receptacles were not shielded from liquid spills, raising the potential for short-circuiting. In three, sediment filters were not contained in opaque housing or otherwise configured so as to inhibit proliferation of algae. The algae could clog membranes or be carried downstream into the dialysate.

3. Insufficent Provision of information or Training by the Manufacturer

a). Equipment specifications

In the twenty-two facilities examined, a total of eleven different versions of water treatment systems were encountered. They are referred to below as "system types." These were primarily reverse osmosis systems. There were also deionizers and ultrafiltration systems, which often supplemented the reverse osmosis systems. Carbon filter systems, which were employed in eleven different facilities, are considered separately from the "system types."

This section covers survey responses indicating inadequate provision by the manufacturer of equipment inventory and warnings of improper operating conditions and procedures (See table 5).

The instructions for one system type did not include requirements for utilities such as electrical power, water pressure and drain size or capacity. The instructions for two types did not include the environmental conditions such as the temperature, humidity, light, noise, or atmospheric pressure necessary for operation or to prevent harm to water treatment instrumentation.

The instructions for one system contained no description of the equipment, including a list of monitors, alarms, and component devices provided as standard equipment. The instructions for three types lacked a listing of safety features and warnings of the consequences of circumventing these features. There was no information about chemicals known to be incompatible with the materials of construction in the instructions for four of the systems.

There were no specifications of the required input water temperature and pressure, the pressure of effluent water at various flow rates, or the maximum output of product water in the guidelines for use of two of the systems. Similarly in two cases, there was no information on appropriate adjustment of monitors, alarms or controls prior to initiation of use.

Three sets of instructions contained no information on procedures to be followed in case of an alarm. Two lacked information on clean-up and sterilization procedures. Another two lacked information on the degree of removal of chemical contaminants to be expected upon purification of specified feed water.

For six systems which produce water whose quality varies with that of the water fed to it, there was no warning of the extent to which product water quality may thereby vary. There was also no statement concerning one or more of the following conditions; that results obtainable with the user's water supply could only be verified by analysis; that the recommended device constituted a minimum system based on the water quality at the time of analysis of the user's water; or that the appropriate water authority should be consulted on variations in feed water that could cause effluent water to exceed acceptable limits of contaminant concentration.

For six of the eleven treatment systems, there was no warning that selection of water treatment equipment is the responsibility of the dialysis physician, or that product water should be periodically tested. In three out of the eleven systems that employed activated carbon filters, there was no warning that exhausted or contaminated carbon is to be discarded.

There was no statement accompanying four of the water treatment system variants that separate processes were to be used to avoid intermixing of regenerated or reconstituted devices returned from medical or potable water users, together with devices returned from nonpotable water users.

There was no information provided regarding chemical compatibility of device construction material for five types of treatment systems. Three systems lacked information regarding on-line monitors of water quality, including operational factors such as temperature that might effect monitor performance. Three types also provided no warnings or precautions on the adverse effects of improper installation or use.

No indication of how to prevent excessive build-up of contaminants in effluent water during the regeneration process was provided for three system types involving automatic regeneration of water treatment systems.

b. Equipment Markings and Operation Instructions

This section covers additional areas of inadequate provision of operating instructions by the manufacturer (See table 6).

The devices in thirteen of the twenty-two facilities were not affixed with prominent warnings regarding substances, such as disinfectants that must be removed before using the effluent water in dialysis. In five of the twenty-two facilities, complete and detailed operating instructions were not provided.

In nine facilities, fittings necessary for proper connections were not identified in the material provided by the manufacturers. In one, the operator did not consider the operating instructions satisfactory, althougn specific criticisms were not recorded. Maintenance instructions were not provided to one facility, and were considered unsatisfactory in another. Again, specific criticisms were not recorded.

4. Miscellaneous Problems with Water Treatment

This section covers potential difficulties stemming from a lack of communication with the local water department, and from incomplete chemical analysis of the treated water (See table 7).

At half of the twenty-two facilities, the water department did not as a rule announce changes in the chemical composition of tap water. This could be a particularly serious omission if the chlorine content were increased, and the ensuing rapid exhaustion of the filter were inadequately monitored. Also at half the locations, the water department did not generally report changes in the quality of tap water. Also the water treatment system at one facility had not been checked to ensure that nitrosamines were not being produced within the system.

B. Dialysate Delivery

The dialysate delivery system must ensure proper mixing of purified water with dialysate concentrate. It also checks that diluted dialysate fed to the dialyzer contains the proper concentration of electrolytes, is heated to physiological temperature, and is delivered at sufficiently low pressure to promote the desired ultrafiltration of water from the blood.

1. Operations, Monitors, Alarms

Notably, according to A.A.M.I. standards the dialysate temperature should be monitored on-line and maintained between 36 and 40 degrees Centrigade at the entry to the dialyzer. Readings outside this range should automatically activate audible and visible alarms, and interrupt dialysate delivery to the dialyzer or blood return to the patient. The temperature control/monitor system should not allow feed dialysate temperature to exceed 42 degrees centigrade.

All facilities reported regular alarm testing and noted that alarm situations cause either dialysate bypass or shut-off of the blood pump. The acceptable temperature ranges in several facilities were 33.9-39.4 degrees centigrade. Others operated with upper limits as high as 41 and 42 degrees. There were no reports of alarm failures. However, in three facilities in which is was possible to manipulate the dialysate pressure so as to control ultrafiltration rate, dialysate circuit pressure was not monitored (See Table 8).

2. Malfunctions or Design Errors

There were few adverse responses in this section of the questionnaire, which focussed on the instrumentation that ensures provision of proper dialysate composition, temperature, flowrate and pressure (See table 8). Still, in four facilities, alarms or warning signals (among those in systems that monitor dialysate temperature, pressure, composition or flowrate) went off without legitimate cause - in one case because of improper internal calibration, in another because of a bulb burnout. Also, in four facilities, there was no alarm system to warn either of two high or too low dialysate circuit pressure.

3. Insufficient Provision of Information or Training by the Manufacturer

a. Equipment specifications

A wide variety of adverse responses were reported in the area of manufacturer provision of specificiations regarding proper operation and protection of the dialysate delivery instrumentation, of which there were ten system types encountered (see Table 9). Note also that there were six types of dialysate fluid.

Four of the ten system types contained no specification of environmental requirements for proper operation, such as temperature, humidity, light, noise or atmospheric pressure, or conditions that may be harmful to the equipment. Missing from one type was information on chemicals known to be incompatible with materials of construction. Also, one system type contained no specification of safety features or warnings of the consequences of circumventing them.

There was no specification for three system types of how to test and calibrate or adjust the monitors, alarms and controls at start-up. Three system types contained no detailed instructions on calibration while five lacked warnings and precautions regarding the adverse effects of improper installation or use.

For one system type each, there were no detailed instructions on operational adjustments, on the operation and significance of alarms, and procedures for discontinuing use, including shutdown, cleanup and sterilization or disinfection.

Nine system types were unaccompanied by a warning that the dialysate concentration monitor should be independently checked. Six were supplied with no indications or statement concerning one or more of the following; whether dialysate pressure monitors register inlet, outlet or mean pressure; or typical

line pressure drop at a fixed flow rate; or a statement that actual pressure at the dialyzer may differ from that indicated by the monitor, depending on the relative height difference between dialyzer and monitor transducer, as well as on the rate of flow in the dialysate lines.

Similarly, six system types were affixed with no indication of whether transmembrane pressure monitors, when provided, measured inlet, outlet or mean pressure of the inlet and outlet on the blood and/or dialysate sides of the dialyzer.

Two types of batch systems not equipped with concentration monitors contained no warning that dialysate concentration is to be checked before initiating dialysis.

Two batch dialysate systems were not affixed with a label on the dialysate concentrate container indicating the volumes of concentrate and water to be mixed. Two of the three dialysate types with proportioning systems were not accompanied by a specification of the necessary ratio of dialysate concentrate and water volumes.

In seven systems that feature air embolism protection, there was no statement of the device's sensitivity to air and foam. For none of the ten system types was there a statement of the sensitivity to air in either blood or saline, or specification of the maximum undetectable flow rate of air.

Six systems types contained no alarm adjustment strategy to be followed by the operator in order to maximize the probability of detecting a blood leak in the extracorporeal circuit. Nine had no warning that hemolysis might occur in the dialyzer in the vent of disturbances such as excessive temperature of hypotonic dialysate, or that hemolyzed blood should not be returned to the patient.

The concentrate label on all six types of dialysate did not specify the nominal measured conductivity of the diluted dialysate at 25 C in millisiemens (ms) or millimhos per centimenter (mmhos/cm). The label on three of the six did not specify the concentration of each electrolyte in the diluted solution in milliequivalents per liter (meq/l). The label on five did not specify the concentration of nonelectrolytes in the diluted solution in milligrams per deciliter (mg/dl).

The aqueous concentrate label for four of the six dialysate types did not contain instructions to thoroughly mix prior to use. In two cases in which bicarbonate is used, the aqueous concentrate label did not contain a warning that bacterial growth may occur in concentrated bicarbonate solutions and that storage time should be determined by the user.

4. Miscellaneous Problems with Dialysate Delivery Systems

In three of the twenty-two facilities, the dialysate delivery system had been modified or changed to adapt it to the operating facility. In one, labels had peeled off several concentrate containers (see Table 10).

C. Extracorporeal Blood Circuit

The extracorporeal blood circuit is comprised of the tubing, connectors and pump that deliver the blood from an artery to the dialyzer, and from the dialyzer to a vein. Care must be taken to ensure sterility, and to prevent clotting or entry of air bubbles into and foaming of the blood.

1. Operations, Monitoring, Alarms

This section covers instances of potentially hazardous operator practice (see Table 11).

The sensitivity of the air/foam detector had not been measured in seven of the twenty-two facilities. In five, there had been occasions when I.V. fluids were administered downstream of the air/foam detector. This is often done when solutions must be administered quickly or in high concentrations such as hypertonic saline for cramps. In two facilities, glass bottles were used to administer IV fluids.

2. Malfunctions or Design Errors

This section covers survey responses indicating inadequate safety features in the design of extracorporeal blood circuitry (see Table 12).

It was reported at three of the twenty-two facilities that if the air/foam detector had not been activated, and the system was operated in a mode that placed the patient at risk, either one or both of the audible and visual indicators did not alert the operator that the air detector had not been activated. In four facilities all told, there were problems with the air/foam detector including insufficient sensitivity and false alarms.

Activation of the disinfection system of the dialysate during dialysis did not result in an alarm visible to the patient in one facility, while in two it was possible for the patient to be dialyzed while the system was in the disinfection/sanitization mode.

In two facilities, electrical receptacles were not shielded from liquid spills.

3. Insufficient Provision of Information or Training by the Manufacturer

a. Equipment specifications

There was a total of three types of extracorporeal blood circuits. In all three cases, the instructions for use of the blood pump did not include

details on the calibration used by the manufacturer to convert speed to flow rate. For one, there was no warning or contraindication concerning improper installation or use.

b) Equipment markings and operating instructions

The operator at one facility considered the manufacturer's guidelines for operation of the the air/foam detector inadequate, although it was not specified why.

D. Dialyzers

The dialyzers consist of the membrane assembly that separates the flowing blood and dialysate fluid, and a plastic housing. The materials must be maintained sterile, and should be compatible with the blood, not causing significant clotting or other reactions. The membranes should be pinhole-free to prevent bulk of blood into the dialysate or vice-versa.

1. Operations, Monitoring, Alarms

This section focuses on potentially hazardous dialyzer usage practices, including reuse and quality control measures (see Table 13).

Eleven of the twenty-two treatment centers practice dialyzer reuse. This requires proper disinfection prior to reuse. Nevertheless, there were no reports of infection of patients exposed to reused dialyzers, as all such facilities did follow disinfection procedures. Quality control measures in two such facilities did not include cell volume. In four, they did not include clearance measurements, i.e., check of the degree of urea removal during dialysis.

2. Malfunctions or Design Errors

In one facility, arterial ports had to be taped to prevent the entry of air into the dialyzer system.

3. Insufficient Provision of Information or Training by the Manufacturers

a. Equipment specifications

The twenty-two facilities inspected employed various combinations of dialyzer supplied by eleven different manfacturers. These are referred to as the eleven "dialyzer types" below.

The instructions for four of the eleven dialyzer types did not include a list of all materials of construction of the dialyzers, the contact blood, or dialysate. The instructions for six types did not include a set-up checklist, including unpacking and inspecting. For four types, the instructions did not list connections to other equipment. For five types, the instructions did not describe conditions for discontinuation of use. For six, they did not cover shut-down procedures.

The instruction for seven did not describe clean-up and sterilization procedures.

For all dialyzer types, there were no instructions for reuse procedures because reuse is not recommended by the manufacturers. Notably, however, reuse was practiced in half of the twenty-two facilities surveyed (See table 14).

4. Miscellaneous Other Problems with Dialyzers

Patient hypersensitivity reactions to dialyzers with symptoms including hives, wheezing and nasal stuffiness were reported in seven of the twenty-two treatment centers. Five of the seven facilities that reported hypersentivity

also practiced dialyzer reuse (see Table 15). However, none of those five facilities reported reactions exclusively with reused dialyzers. Three facilities reported reactions only upon initial use while the other two facilities reported hypersensitivity upon exposure to both new and reused dialyzers.

Three facilities reported incidence of mild to moderate pyrogenic reactions. Two practiced dialyzer reuse. One of the facilities that practiced reuse reported reactions with both new and reused dialyzers while the other did not indicate whether new or reused dialyzers were in use.

In eight facilities, there were incidents of blood membrane interactions. These included hypersentivity to cuprohane, respiratory distress, seizure and one incident of cardiac arrest. There is no direct evidence that these reactions were caused by improper or inadequate procedures or membranes, however.

In one facility a dialyzer problem had been caused by packing. The arterial ports of the membrane assembly were cracked upon arrival (See table 16).

IV. CONCLUSIONS

The above findings indicate that in the routine operation of dialysis treatment centers, a number of inappropriate procedures are practiced. The study also discovered instances where manufacturer information is lacking and some instances of poor system design or system malfunctions. Notably, these circumstances are not found in the majority of centers and do not appear to have caused harm to dialysis patients. Nonetheless, there were significant numbers of adverse responses to many important questions.

In nearly half of the facilities examined, warning and alarm systems of water treatment devices were not periodically calibrated. In the same number

of facilities, a main electrical failure in these devices was not indicated by an audible alarm. The lack of alarms on the effluent water's conductivity monitor and the lack of shutdowns or alternative paths for incidents where monitored parameters exceeded tolerable limits were found in a number of facilities.

Inadequate provision of water treatment equipment specifications was noted in a wide variety of subject areas including safety features and tne consequences of circumventing them, chemical compatibility of materials of construction, procedures to be followed in case of alarm, and warnings on adverse effects of improper installation or use. In more than half the facilities inspected, water treatment devices were not affixed with prominent warnings regarding substances such as disinfectants that must be removed before using product water in dialysis. Half the facilities noted a lack of communication from the local water department on matters of altered water composition and quality.

With respect to dialysate delivery system, although the A.A.M.I. standard recommends that dialysate temperature not exceed 40 degrees Centrigade, facilities operated with maximum tolerable limits of 41 and 42 degrees. As noted regarding equipment specifications for after treatment systems, the materials supplied along with dialysate delivery systems frequently lacked warnings on the effects of improper installation or use. Nine such systems lacked warnings that blood hemolysis was possible in the dialyzer in the event of, for example, excessive temperature or hypotonic dialysate, and that hemolyzed blood should not be returned to the patient. The labelling of the dialysate concentrate containers was often inadequate, lacking, for example, instructions to mix thoroughly prior to use.

Responses were generally favorable regarding extracorporeal blood circuits. However, it was frequently reported that the sensitivity of the air/foam detector had not been measured.

As was noted with respect to water treatment, dialysate delivery and extracorporeal blood circuit systems, it was also true of the dialyzers that manufacturer equipment specification and instructions were frequently found lacking.

Half the facilities reported practicing dialyzer reuse. However, only one facility indicated a problem with reuse. This facility noted an increase in thrombosis, but did not report any serious consequences as a result of this. All eleven facilities practicing reuse indicated satisfaction with the procedure. Hypersensitivity reactions were less frequently noted with reused than with new dialyzers. This is consistent with the notion that new systems contain undesirable chemicals that are only leached out after first use. Pyrogenic reactions were reported on both new and reused dialyzers.

V. RECOMMENDATIONS

Although this study did not find any serious consequences as a direct result of kidney dialysis, a number of improper practices were discovered. The findings of this study suggest that uniform guidelines for the operation of hemodialyzers, along the lines suggested by the A.A.M.I. standards, and requirement of manufacturers with regard to equipment specifications and operating instructions, are necessary and should be enforced. The following are specific recommendations to further ensure patient safety.

A. Water Treatment

To avoid bacterial growth, disinfection must be carried out when a system component is being regenerated, and applied to piping and other system components.

To avoid adverse patient reactions, treated water should be analyzed for chlorine and chloramine contents, and maximum tolerable chlorine and aluminum levels should be enforced.

Furthermore, to avoid short-circuiting, electrical receptacles must be shielded from liquid spills. In addition, electrical failures must be indicated by an audible alarm.

Complete operating and maintenance instructions should be supplied. Equipment specifications should include electrical power requirements, a complete description of all equipment, and a list of safety features including the consequences of circumventing them. There must be information on the proper setting of monitors, alarms and controls and on procedures to be followed in case of alarm.

Required temperature and pressure of feed water, and chemicals incompatible with the equipment should also be specified.

There should be prominent warnings regarding substances, such as disinfectants, that must be removed before applying effluent water to dialysis.

Close contact with the city water departments should be established in order to monitor gross changes in tap water composition and quality.

B. Dialysate Delivery

Dialysate circuit pressure must be monitored to ensure proper filtration of blood water. The significance of transmembrane pressure indications should

be clarified by the manufacturer. Alarm systems should alert the operator to excursions from optimal pressure ranges, and all safety features should be specified, as well as the consequences of circumventing them.

Information should be supplied that specifies how to test, calibrate and adjust the monitors, alarms and controls. The dialysate concentration is a key determinant of the proper functioning of the dialyzer as a cleanser of the blood. Thus, the dialysate concentration monitor should be independently checked. With batch systems not equipped with concentration monitors, the dialysate concentration should be checked prior to initiation of dialysis.

In the case of batch systems, the dialysate concentrate container labels should indicate the volumes of concentrate and water that are to be mixed. With proportioning systems, the ratio of dialysate concentrate and water volumes to be mixed should be specified. The concentrate label should in all cases specify the concentrations of electrolytes and nonelectrolytes in the diluted dialysate.

In addition, the sensitivity range of air/foam alarms should be specified. There should also be prominent warnings that hemolysis may occur in the dialyzer in the event of a disturbance such as excessive temperature or hypotonic dialysate, and that hemolyzed blood should not be returned to the patient.

C. Extracorporeal Blood Circuit

Since entry of air into the blood is dangerous, the sensitivity of the air/form detector should either be specified or measured.

It should not be possible for the patient to be dialyzed while the system is in the disinfection/sanitization mode.

D. Dialyzers

Quality control measures must include urea clearance measurements.

Manufacturer instructions should include a set-up checklist, including unpacking and inspecting, and guidelines on connections to ancillary equipment, reuse, clean-up and sterilization and shutdown procedures, and conditions for discontinuation of use.

E. Dialyzer Reuse

The question of the efficacy and side-effects of dialyzer reuse merits further consideration. The limited observations reported here suggest that this procedure does not increase the risk of adverse reaction to the patient. Thus, the procedure may be warranted both for economic reasons and for minimizing exposure to chemicals contained in unused dialysers. Further study is recommended.

APPENDIX A

FIGURE 1. - Functional Diagram of Mini-II Dialysate Supply Unit

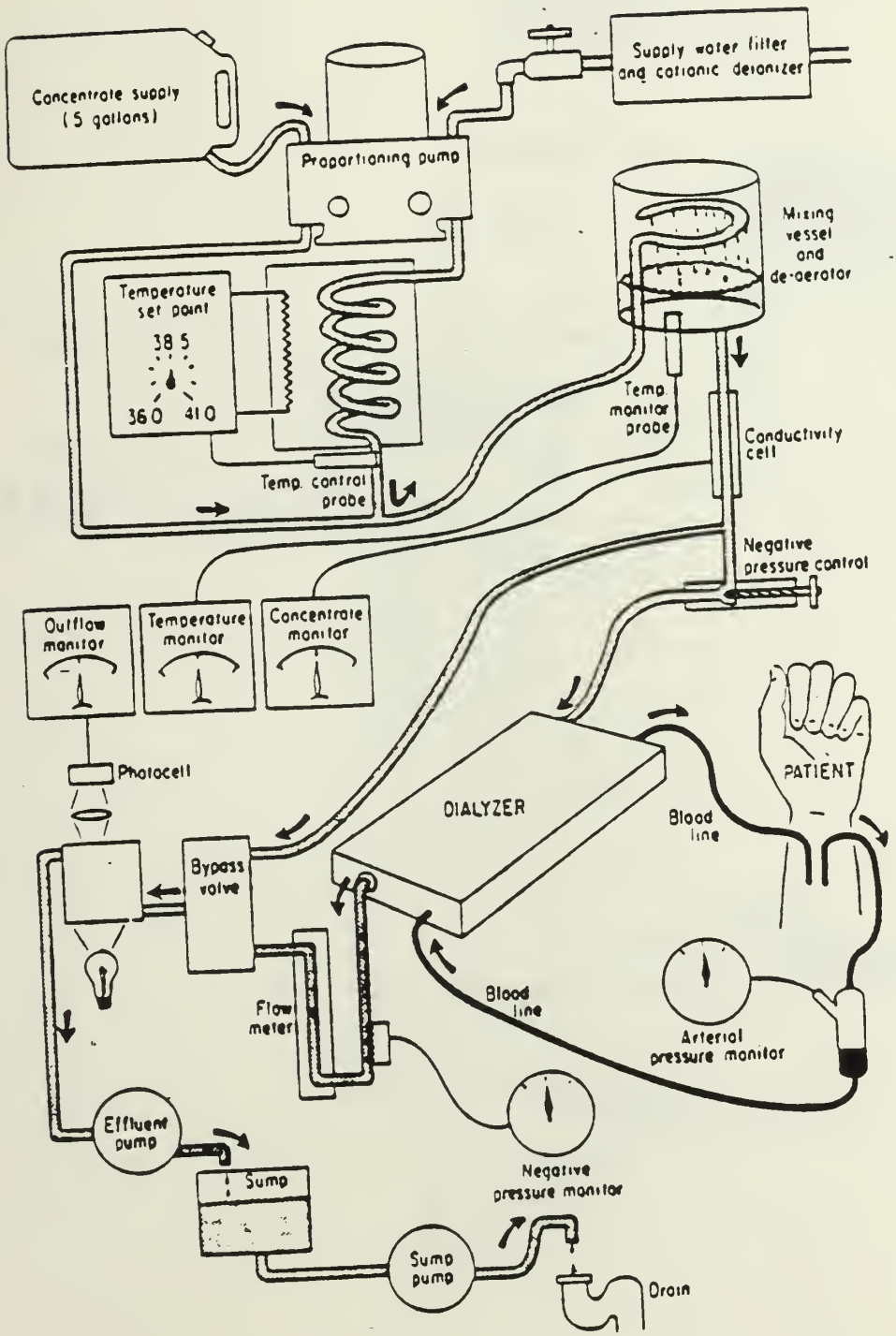
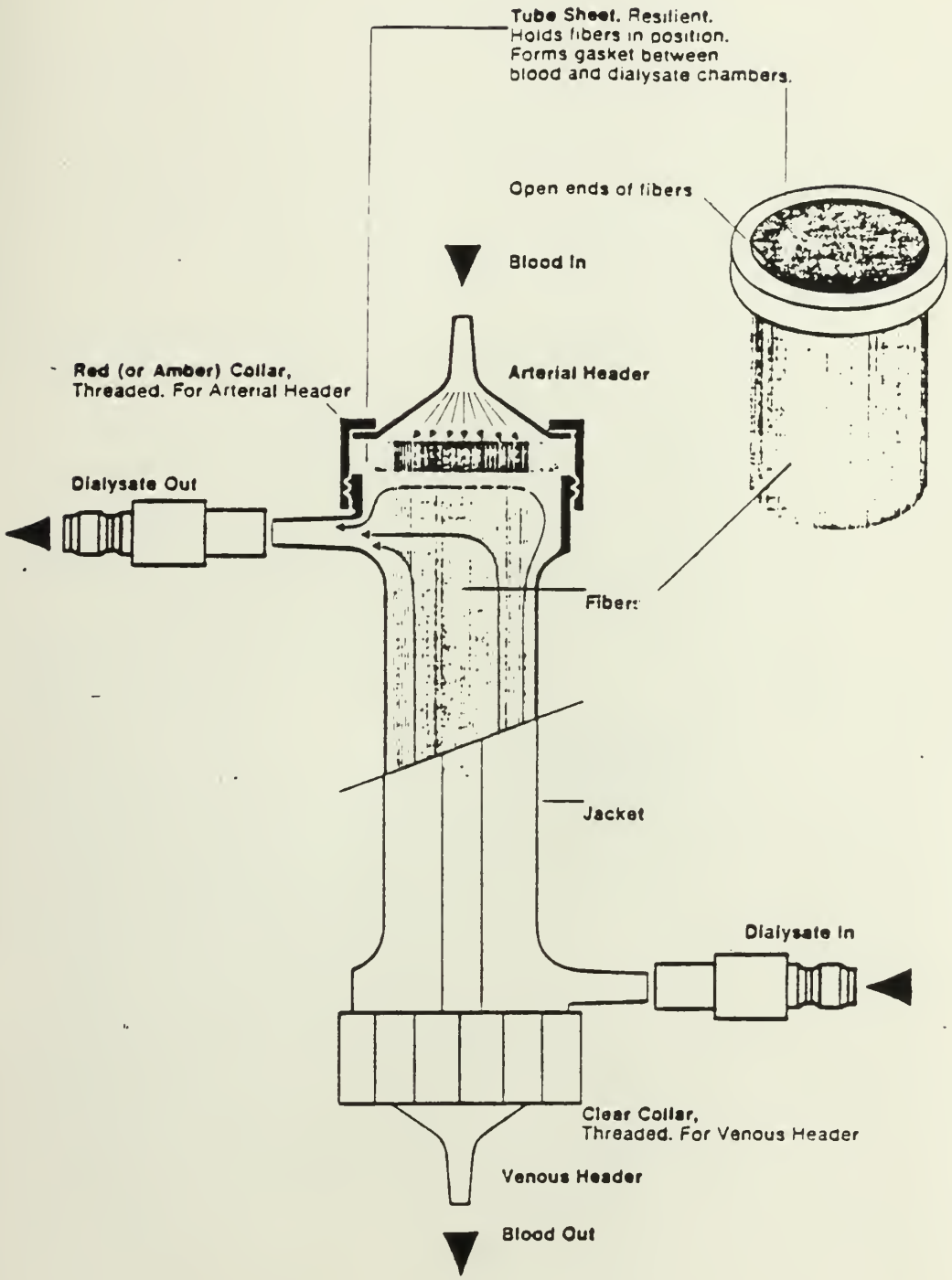


FIGURE 2. - The Capillary Artificial Kidney



APPENDIX B

A. INTERVIEW AND EQUIPMENT OBSERVATIONS

QUESTIONS	YES	NO	N/A	COMMENTS
Water Treatment Equipment				
1. What water purification system(s) is/are used: a. Manufacturer _____ b. Type(s) of Device _____ c. Age of system _____				
2. Person(s) responsible for (name and title): a. Equipment Operation: _____ b. Equipment Maintenance: _____				
3. Device Markings. The following information is affixed to each water treatment device or system: (AAMI 3.1.3.1) a. Name and address of manufacturer:				
b. Trade name and type of device:				
c. Model and serial number:				
d. A warning that product literature should be read before use (if appropriate):				
e. Prominent warnings about substances (e.g., disinfectants) that must be removed from the device before using the product water for dialysis; and				
f. Identification of fittings, when necessary, to prevent improper connections.				
4. Who installed the equipment? _____				
5. Are complete and detailed instructions for use provided?				

QUESTIONS	YES	NO	N/A	COMMENTS
6. Do you consider the operating instructions satisfactory? Why?				
7. Are maintenance instructions provided?				
8. Do you consider the maintenance instructions satisfactory? If not, why?_____				
9. Are warnings and contraindications concerning improper installation or use provided?				
10. Has the system been modified or changed to adapt to your facility?				
If modified or changed, who made the change: manufacturer, consultant, staff member or other? _____				
11. What type (material of construction) of tubing or piping carries the water from the purification system to the dialysate delivery system? _____				
12. Does your facility have contact with the water department which supplies your water?				
a Does the water department contact your facility when they change the chemical composition of the water?				
b. Does the water department contact your facility when they make any changes in the source of water?				
13. a. How is regeneration accomplished? _____ b. Who is responsible for checking to see that it is done?				

QUESTIONS	YES	NO	N/A	COMMENTS
14. a. Is the equipment disinfected?				
b. If yes, when? _____				
15. Are bacterial counts performed to determine the quality of purified water?				
a. Are the total number of viable bacteria 200/ml or less?				
b. How often are counts performed?				
c. Where is the sample site for the testing? _____				
d. How are the cultures performed? _____				
16. Is there an alarm on the conductivity monitors?				
a. Has the alarm been tested?				
b. How often is it tested? _____				
c. What are the acceptable limits for conductivity? _____				
d. What happens when those limits are exceeded? _____				
17. What other warning and alarm systems are included in the water treatment equipment? _____				
a. How are these checked? _____				
b. How often are they checked?				
c. What are the acceptable limits? _____				
d. What happens when the alarm is set off? _____				

QUESTIONS	YES	NO	N/A	COMMENTS
18.				
a. Are the warning and alarm systems calibrated periodically?				
b. How often are warning and alarm systems calibrated? _____				
c. How many times has the alarm system been activated at the appropriate time? _____				
19.				
a. Have you had any alarm failures (cases where an alarm or warning signal should have been given but was not)?				
b. If yes, explain. _____				
20. Is chlorine/chloramine removal by carbon filters monitored?				
a. How is monitoring performed? _____				
b. How often is monitoring performed? _____				
21. Is the pH of the water monitored?				
a. Where is the water sample taken from? _____				
b. When is the pH monitored? _____				
c. What are the limits of acceptability? _____				
22. What if any pretreatment of water is performed? _____				
23. Regenerated or Reconstituted Devices: (AAMI 3.2.3.3)				
a. Are all of the components of these devices disinfected at the time of regeneration or reconstitution?				

QUESTIONS	YES	NO	N/A	COMMENTS
b. Are separate processes employed to ensure no intermixing of devices or their components between devices returned from medical or potable water users and devices returned from nonpotable water users?				
24. Deionization. Is there an indicator which reveals the status of the deionization equipment?				
25. Are other analyses performed to determine the quality of purified water?				
a. What other analyses are performed?				Is the Maximum Level? (mg/l)
Calcium				2 (0.1 mEq/l)
Magnesium				4 (0.3 mEq/l)
Sodium				70 (3 mEq/l)
Potassium				8 (0.2 mEq/l)
Fluoride				0.2
Chlorine				0.5
Chloramines				0.1
Nitrate (N)				2
Sulfate				100
Copper, Barium, Zinc				each 0.1
Aluminum				0.01
Arsenic, Lead, Silver				each 0.005
Cadmium				0.001
Chromium				0.014
Selenium				0.09
Mercury				0.0002
b. How often are they performed?				

YES	NO	N/A

QUESTIONS	YES	NO	N/A	COMMENTS
26. Do automated water treatment regeneration devices prevent excessive levels of contaminants such as sodium chloride in product water during regeneration? (AAMI 3.2.3.8)				
27. Deionization. Is the final effluent monitored continuously to produce water of one megohm-cm or greater resistivity? (AAMI 3.2.3.4)				
a. Is the resistivity monitor for the tank deionizer temperature compensated?				
b. If not, is the water temperature maintained at 25°C? (AAMI 3.2.3.4)				
c. Has the system been shown to not produce nitrosamines?				
d. If no, is feed water for deionization systems pretreated with activated carbon filtration? (AAMI 3.2.3.4)				
28.				
a. Reverse Osmosis. Is system monitored continuously for performance (salt passage rate)? (AAMI 3.2.3.5)				
b. Is the conductivity of feed and passage water monitored continuously?				
29. Carbon Filter Media. Is exhausted carbon filter media discarded and replaced with new media? (AAMI 3.2.3.7)				
30. Do sediment filters have an opaque housing or other means to inhibit proliferation of algae? (AAMI 3.2.3.6)				
31.				
a. Is water purification subsystem (i.e. piping, storage systems) disinfected?				
b. How often? _____				
c. What agent is used? _____				

QUESTIONS	YES	NO	N/A	COMMENTS
* d. Are there dead ends, sharp angles, or nonfilled pipes which may make adequate disinfection of piping systems impossible? If yes, comment. _____ _____				
32. Have you had any problems with this equipment? Explain, if yes _____ _____ _____ _____				
33. General Safety Requirements: (AAMI 3.4.1) Does each device exhibit the following minimum safety features:				
a. Safe configuration which will be entered in the event of a variable excursion outside of control limits;				
b. Monitors located and of such sensitivity as to minimuze the number of false alarms while adequately protecting the patient;				
c. Operating controls positioned so as to minimize inadvertent resetting;				
d. Monitor design so that the monitor cannot be turned off while the patient is at risk, except for brief necessary periods of manual control with the operator in constant attendance;				
e. Audiole alarms that are at least 70 decibels ("A" scale) at 3 meters and which cannot be muted for more than 180 seconds; and				
f. Design that facilitates cleaning so as to minimize entrapment of blood and other contaminants.				

QUESTIONS	YES	NO	N/A	COMMENTS
34. Electrical Safety Requirements. The following requirements for electrical safety are met by each device: (AAMI 3.4.2)				
a. An electrical ground is provided whenever necessary according to normally accepted practice;				
b. Metals in electrical apparatus or components are corrosion resistant when used as specified or in accordance with normally accepted procedures;				
c. Electrical receptacles are shielded from liquid spills;				
d. Elecrical circuits are separate from hydraulic circuits and adequately isolated from fluid leaks;				
e. Main electrical failure to a system and its components is indicated by an audible alarm.				
Dialysate Delivery System				
35. What dialysis machines are used: a. Type: _____ 1. _____ 2. _____ 3. _____ b. Manufacturer: _____ 1. _____ 2. _____ 3. _____ c. How old is the equipment? _____ _____				

QUESTIONS	YES	NO	N/A	YES	NO	N/A	YES	NO	N/A
	TYPE 1			TYPE 2			TYPE 3		
36. Device Markings. The following information is affixed to the device: (AAMI 3.1.4)									
a. Trade name;									
b. Model and serial number;									
c. Name and address of manufacturer;									
d. Requirement for external ground, if any, and;									
e. Identification of controls and displays.									
37. All monitors and alarms designed for bedside surveillance are placed so that all controls and displays can be clearly seen by patients lying in an adjacent bed or by attending personnel standing at the bedside or both? (Vision corrected to 20/20)(AAMI3.3.6.1)									
38. If a central delivery system is used, where is heating accomplished?									
39. Are complete and detailed instructions for use provided?									

Comments:

QUESTIONS	YES	NO	N/A	COMMENTS
40. Do you consider the operating instructions satisfactory? If not, why not? _____				

QUESTIONS	YES	NO	N/A	YES	NO	N/A	YES	NO	N/A
	TYPE 1			TYPE 2			TYPE 3		
41. Are warnings and contraindications concerning improper installation or use provided?									

QUESTIONS	YES	NO	N/A
42. Have you modified or changed the equipment to adapt it to your facility?			
a. If modified, who made the modifications (person's title and employer)? _____			
b. When were changes or modifications made? _____			
c. What changes or modifications were made? _____			
43. Who is the manufacturer of the dialysate concentrate? _____			
44. What is the chemical composition of the dialysate concentrate which is used? _____			

QUESTIONS	YES	NO	N/A	COMMENTS
45. Who is responsible for adding the concentrate? _____				
46. a. How is dialysate concentration and conductivity measured? _____ b. How often is it measured? _____ c. What are the limits for acceptability of the concentration and conductivity? _____				
47. Have you had any problems with the concentrate? If yes, comment. _____				
48. Have you had any problems with the dialysate concentration? If yes comment. _____				
49. a. Who is responsible for cleaning and disinfecting the dialysis machines? _____ b. What agent(s) is/are used? _____ c. What concentration of agent(s) is used? _____ d. How long is the agent left in contact with the equipment? _____ e. What testing is performed to ensure the complete removal of disinfectant prior to use of the equipment? _____				

QUESTIONS	YES	NO	N/A	COMMENTS
f. How often is the equipment tested? _____				
g. Are dialysate cultures taken?				
h. How often is the dialysate tested? _____				
i. Are microbial counts of the dialysate less than 2000/ml? (AAMI 3.2.1.2.)				

50. Temperature Monitor. (AAMI 3.3.6.2)	YES	NO	N/A	YES	NO	N/A	YES	NO	N/A
	TYPE 1			TYPE 2			TYPE 3		
a. Is the temperature of the dialysate measured on line?									
b. Where is the temperature of the dialysate measured?									
c. What are the limits for the temperature?									
d. Are temperature readings in centigrade?									

Comments:

51. Temperature Alarm (AAMI 3.3.6.2)	YES	NO	N/A	YES	NO	N/A	YES	NO	N/A
	TYPE 1			TYPE 2			TYPE 3		
a. Is there an alarm or warning signal which warns of temperatures which are outside of acceptable limits (dialysate ≤42°C.)?									
b. Has the alarm or warning signal been tested?									
c. What are the acceptable limits?									
d. What happens when the alarm is set off?									

Comments:

QUESTIONS	YES	NO	N/A	COMMENTS
52. Have you had any alarm failures (i.e. any cases where the alarm or warning signal should have been given but was not)?				
53. Have there been cases when the alarm or warning signal was given but should not have been given?				
54. How is the dialysate flow rate controlled? _____ _____				
55. In systems which are capable of manipulating dialysate pressure for control of ultrafiltration, is the dialysate circuit pressure monitored?(AAMI 3.3.6.3)				
a. Who sets the dialysate pressure? _____				
b. What are the limits for acceptability? _____ _____				
c. Where is the pressure monitored? _____ _____				
d. Is monitor tested for accuracy?				
e. If tested, is monitor accuracy ± 20 mmhg or ± 10% of the reading, whichever is greater? (AAMI 3.3.6.3)				
56. Is there an alarm system which warns of unacceptable dialysate circuit pressure both two high and two low? (AAMI 3.3.6.3)				
a. Does alarm system activate audible and visual indicators of the alarm condition?				
b. Are alarms manually adjustable by the operator or factory preset? _____ _____				
c. Are manually adjustable alarms easily set and understood?				
d. Has the alarm system been tested?				
e. How often is it tested? _____ _____				
f. Has there been any alarm failures?				

QUESTIONS	YES	NO	N/A	COMMENTS
57. Does the dialysate delivery system have a blood leak detector which warns of a blood leak into the dialysate?				
a. Is there an alarm system attached to the blood leak detector?				
b. Has the alarm been tested?				
c. How is the threshold level of the detector chosen? _____				
d. Who is responsible for setting the threshold? _____				
Extracoporeal Blood Circuit				
58. Who is responsible for accessing the patients' circulation? ____				
59. Who is the manufacturer of the needles? _____				
60.				
a. Are single needle systems in use?				
b. How many are used?				
c. Have you experienced any problems with the use of these needles?				
61.				
a. What blood tubings and accessories are in use? _____				
b. Who is the manufacturer of the blood tubing and accessories in use? _____				
c. Have you had any problems with the blood tubing and assessories? If yes, comment. _____				
d. Have you had cases where the blood tubing connectors are inappropriate?				
e. Have you had any leaks in components or fittings?				

QUESTIONS	YES	NO	N/A	COMMENTS
62.				
a. Have latex sample sleeves failed to reseal following punctures with hypodermic needles?				
* b. Do manufacturers' instructions place restrictions on the needle size to be used?				
63. Do you reuse blood tubings and accessories?				
a. What disinfectant is used? ____				
b. How long is the disinfectant in contact with the tubings or accessories? _____				
c. Who is responsible for this reuse procedure? _____				
d. Have you had any problems with the practice? If yes, comment. _____ _____				
64. Blood Circuit Pressure Monitor. (AAMI 3.3.6.5)				
a. How is blood circuit pressure monitored? _____				
b. Is blood circuit pressure monitored in the blood circuit distal to the dialyzer?				
c. Is there an alarm which warns of unacceptable pressures both high and low?				
d. Is the alarm tested?				
e. How often is testing performed?				
f. Is the alarm calibrated?				
g. How often is it calibrated? _____				
h. Do pressures outside of the alarm limits shut off the blood pump (if used) and activate audible and visible alarms?				

QUESTIONS	YES	NO	N/A	COMMENTS
65. What air/form detectors are in use? _____				
a. Who is the manufacturer of the detector? _____				
b. Are manufacturers' operational guidelines adequate?				
c. Does the detector initiate both audible and visual alarms? (AAMI 3.3.6.8)				
d. Does an alarm condition or loss of power to the detector cause an integral or external blood pump to be turned off and cause the occlusion of the venous line distal to the point of monitoring?				
e. Is a means provided for manual release of the venous clamp to allow for return of blood in emergency situations?				
f. If the detector has not been activated and the system is being operated in a mode where the patient is at risk, do both audible and visual indicators alert the operator that the air detector is not activated? (AAMI 3.3.6.8)				
66. Air/foam detectors: a. Is the sensitivity of the air/foam detector measured?				
b. How often?				
c. Have you had any problems with the detector? If yes, comment. _____ _____				
67. a. Are there any occasions where IV fluids are administered after the air/foam detector?				
b. When? _____ _____				
68. Are glass bottles used to administer IV fluids?				

QUESTIONS	YES	NO	N/A	COMMENTS
69. Are IV fluids administered before or after the blood pump? _____ _____				
70. Disinfection Protection. (AAMI 3.3.6.9) a. Does activation of the disinfection system of the dialysate circuit during dialysis result in an alarm visible to the patient?				
b. Is it impossible for the patient to be dialyzed while the system is in the disinfection/ sanitation mode?				
71. What infusion pumps for anti-coagulation are in use? _____				
a. Who is the manufacturer of the pumps? _____				
b. Are the manufacturer's operational and maintenance guidelines adequate?				
c. Are you satisfied with the performance of the infusion pump? If no, comment. _____ _____ _____				
d. Who is responsible for the operation and maintenance of the equipment? _____				
72. Is heparin added before or after the blood pump?				
73. Who is responsible for assuring that the prescribed amount of heparin is delivered to the extracorporeal circulation? ___ _____				
74. Have you experienced any problems with the equipment in use? If yes, explain. _____ _____ _____				

QUESTIONS	YES	NO	N/A	COMMENTS
75. Have you had any cases where the connectors do not fit together properly?				
76. What blood pumps are in use? A. _____ B. _____				
77. Who is the manufacturer? A. _____ B. _____				
78. Who is responsible for its operation? _____ _____				
79. How is the speed of the blood pump set? A. _____ B. _____				
80. Who is responsible for setting the speed? _____ _____				

	TYPE A			TYPE B		
	YES	NO	N/A	YES	NO	N/A
81. Are the rotating parts of the pump shielded from the operator by a safety cover?						
82. Are the electrical components of the blood pumps shielded from spills?						
a. Are the pumps designed for operation with different segment diameters or with single/dual segments?						
b. If yes, does the blood flow rate display reflect the choice of segment?						

QUESTIONS	YES	NO	N/A	YES	NO	N/A
	TYPE A			TYPE B		
83. a. Do you consider the operating instructions satisfactory?						
b. Why?						
84. a. Is a means provided for manual operation of the blood pump?						
b. What means is provided?						
85. Are warnings and contra-indications concerning improper installation or use provided?						

Comments:

QUESTIONS	YES	NO	N/A	COMMENTS
86. Are you satisfied with the performance of the equipment? If no, comment.				
87. Have you experienced any problems with the blood pumps? If no, comment.				

QUESTIONS	YES	NO	N/A	COMMENTS
88. General Safety Requirements of Extracoporeal Blood Circuit (AAMI 3.4.1) Does each device exhibit the following minimum safety features:				
a. safe configuration which will be entered in the event of a variable excursion outside of control limits;				
b. monitors located and of such sensitivity as to minimize the number of false alarms while adequately protecting the patient;				
c. operating controls positioned so as to minimize inadvertent resetting;				
d. monitor design so that the monitor cannot be disabled while the patient is at risk, except for brief necessary periods of manual control with the operator in constant attendance;				
e. audible alarms which cannot be muted for more than 180 seconds;				
f. design that faciliates cleaning so as to minimize entrapment of blood and other contaminants.				
89. Electrical Safety Requirements. (AAMI 3.4.2) The following requirements for electrical safety are met by each device:				
b. An electrical ground is provided whenever necessary according to normally accepted practice;				
c. Metals in electrical apparatus or components are corrosion resistant when used as specified or in accordance with normally accepted procedures;				
d. Electrical receptacles are shielded from liquid spills;				
e. Elecrical circuits are separate from hydraulic circuits and adequately isolated from fluid leaks;				
f. Main electrical failure to a system and its components is indicated by an audible alarm.				

Dialyzers

QUESTIONS	YES	NO	N/A	COMMENTS
90. What type(s) of dialyzers is/are in use? _____ A. _____ B. _____ C. _____ D. _____ E. _____ F. _____				
91. Who is the manufacturer? _____ A. _____ B. _____ C. _____ D. _____ E. _____ F. _____				
92. Who is responsible for their operation? _____ _____				
93. Who is responsible for their maintenance? _____ _____				
94. Are complete and detailed instructions for use provided?				
95. Do you consider the operating instructions satisfactory:				(If no, comment)
A. for Type A? _____ _____				
B. for Type B? _____ _____				
C. for Type C? _____ _____				
D. for Type D? _____ _____				
E. for Type E? _____ _____				
F. for Type F? _____ _____				

QUESTIONS	YES	NO	N/A	COMMENTS
96. How are the dialyzers packed when initially received? A. Type A _____ B. Type B _____ C. Type C _____ D. Type D _____ E. Type E _____ F. Type F _____ _____				
97. Have you had any problem with the dialyzers which were cause by the packing?				
98. Have you had any cases of blood membrane interactions? i.e., platelet, WBC, or fibrin disposition or activation of complement cascade)? If yes, comment. _____ _____ _____				
99. Are you satified with the performance of the dialyzer? If no, comment. _____ _____				
100. Who is responsible for monitoring dialyzer performance? _____ _____				
101. Have you had any cases of nonfitting connections?				
Explain _____ _____ _____				

QUESTIONS	YES	NO	N/A	COMMENTS
102. a. Do you practice dialyzer reuse?				
b. If so, who is responsible for the operation, disinfection and maintenance of the reuse equipment? _____				
c. How long have you been practicing reuse? _____				
103. a. Do you practice manual or automated reuse? _____				
b. How are the dialyzers rinsed out? _____				
104. a. What disinfecting agent do you use in the reprocessing of dialyzers? _____				
b. How long does the disinfectant stay in contact with the dialyzer? _____				
c. What concentraction of disinfectant is used? _____				
d. Are you using bleach in any aspect of your reused procedures?				
105. Is treated or raw water used in the reprocessing of dialyzers?				
106. a. Is testing performed after processing to ensure that disinfectant was in contact with the dialyzer?				
b. If disinfectant is not found, is the reprocessing repeated prior to reuse?				

QUESTIONS	YES	NO	N/A	COMMENTS
107. a. Are there testing procedures to assure removal of the disinfectant from the dialyzer?				
b. How often is testing performed? _____				
108. a. Do quality control measures include: cell volume?				
ultrafiltration				
clearance measurements				
b. Identify the testing and the criteria for acceptability: Testing _____ Criteria _____				
c. How often are these parameters tested? _____				
109. Do reprocessing records include: a. who did reprocessing?				
b. date treated.				
c. date of reuse?				
110. a. Are there criteria for any dialyzers that are not to be used?				
b. What are the criteria? _____				
111. When components of the dialyzer circuits are removed for reprocessing procedures, are they reattached to the same dialyzers?				
112. Have you had any problems with your reuse program? If yes, comment. _____				

QUESTIONS	YES	NO	N/A	COMMENTS
113. Are you satisfied with your reuse program? If no, comment. _____ _____ _____				
114. Have you had any hypersensativity reactions?				
a. If yes, were they mild, moderate, or severe reactions?				
b. If yes, did the reactions occur while a new or a reused dialyzer was being used?				
115. Have you had any incidences of pyrogenic reactions?				
a. If yes, were they mild, moderate, or severe reactions? _____				
b. If yes, did the reactions occur while a new or a reused dialyzer was being used? _____				
116. Have you changed dialyzer manufacturers in the past two years?				
If yes, why? _____ _____ _____				

B. MANUFACTURER'S INFORMATION

QUESTIONS (Water Treatment)	YES	NO	N/A	YES	NO	N/A	COMMENTS
	TYPE A			TYPE B			
*1. Do instructions for use include: (AAMI 3.1.2.2 & 3.1.3.2)							
a. Requirements for utilities, such as electrical power, water pressure, and drain size or capacity;							
b. A list of accessories provided by the manufacturer of the system that may be used with the power provided by the apparatus;							
c. Total available power in volts and amps of accessory outlets;							
d. Physical dimensions and weight of the equipment;							
e. Environmental conditions, such as temperature, humidity, light, noise, or atmospheric pressure, necessary for operating the equipment or known to be detrimental to equipment function;							
f. A description, where appropriate, of the equipment, including a list of monitors, alarms, and component devices provided as standard equipment;							
g. Safety features and warnings concerning the consequences if these features are circumvented;							
h. Information about chemicals which are known to be incompatible with materials used in the device;							
i. instructions for unpacking and initial inspection;							
j. set-up checklist?							
k. pre-use testing and calibration?							
l. specifications such as required input water temperature and pressure, pressure of product water at various flow rates, and maximum output of product water?							

QUESTIONS	YES	NO	N/A	YES	NO	N/A	COMMENTS
	TYPE A			TYPE B			
m. materials of construction, identified generically, that contact water?							
n. connections to other equipment?							
o. initiation of use with appropriate adjustment of monitors, alarms, and controls?							
p. operational adjustments?							
q. alarm procedures?							
r. discontinution of use?							
s. shut-down?							
t. clean-up and sterilization procedures?							
u. Specified water supply or operating conditions that may cause the device to fail;							
v. Expected degree of removal for chemical contaminants after purification of specified input water;							
w. In the case of systems whose product water quality varies with the input water quality, warnings that actual product water quality may vary substantially from the value for specified input water, that the expected results for the user's water can only be verified on the basis of analysis of the user's water, that the recommended device(s) is/are a minimum system based on water quality at the time of analysis of the user's water, and that the appropriate water authority should be consulted regarding variations in input water that may cause the output water to exceed the limits;							
x. In the care of activated carbon filters, a warning that exhausted or contaminated carbon should be discarded;							

QUESTIONS	YES	NO	N/A	YES	NO	N/A	COMMENTS
	TYPE A			TYPE B			
y. Warnings that selection of water equipment for dialysis is the responsiblility of the dialysis physician and that product water should be tested periodically;							
z. Typical life of components that are nondurable or require periodic regeneration or reconstitution and a statement that information on expected component life relative to the user's feed water is available upon request;							
aa. A statement that separate processes were used to avoid intermixing of regenerated or reconstituted devices returned from medical or potable water users and devices returned from process or nonpotable water users, as well as a description of the method used;							
bb. Information about chemicals known to be incompatible with materials used in the device;							
cc. Information pertaining to on-line monitors of water quality, including operational factors that may affect monitor performance, e.g., temperature;							
dd. For automatic water treatment regeneration devices, identification of the mechanism that prevents excessive levels of contaminants in product water during regeneration;							
ee. Conditions and procedures for storage;							
ff. Warnings and precautions about known adverse effects from improper installation or use;							
gg. A statement that information about the limits of performance specifications is available on request.							

QUESTIONS	YES	NO	N/A	YES	NO	N/A	COMMENTS
	TYPE A			TYPE B			
*2. Do maintenance instructions include: (AAMI 3.1.3.2)							
a. preventive maintenance?							
b. recommended intervals for maintenance?							
c. troubleshooting guidelines?							
d. illustrations and service information?							
e. repair procedures?							
f. parts lists?							
g. schematic electrical and hydraulic circuit drawings?							

Dialysate Delivery System	YES	NO	N/A	YES	NO	N/A	YES	NO	N/A
	TYPE A			TYPE B			TYPE C		
3. Product Literature. Do instructions for use include: (AAMI 3.1.2.2 and 3.1.4.2)									
a. Requirements for utilities, such as electrical power, water pressure, and drain size or capacity;									
b. A list of accessories provided by the manufacturer of the system that may be used with the power provided by the apparatus;									
c. Total available power in volts and amps of accessory outlets;									
d. Physical dimensions and weight of the equipment;									
e. Environmental conditions, such as temperature, humidity, light, noise, or atmospheric pressure, necessary for operating the equipment or known to be detrimental to equipment function;									
f. A description, where appropriate, of the equipment, including a list of monitors, alarms, and component devices provided as standard equipment;									
g. Safety features and warnings concerning the consequences if these features are circumvented;									
h. Information about chemicals which are known to be incompatible with materials used in the device;									

QUESTIONS	YES	NO	N/A	YES	NO	N/A	YES	NO	N/A
	TYPE A			TYPE B			TYPE C		
i. Installation and start-up procedures expected of the user, including: (1) instructions for unpacking,									
(2) initial inspection,									
(3) start-up check list,									
(4) assembly,									
(5) testing, and calibration or adjustments of monitors, alarms, and controls;									
j. Detailed instructions for use, including: (1) calibration,									
(2) connections to other equipment,									
(3) operational adjustments, and									
(4) operation and meaning of alarms;									
k. Procedures for discontinuing use, including shutdown, clean-up, and sterilization or disinfection;									
l. Maintenance and service instructions, including: (1) preventive maintenance,									
(2) trouble-shooting guidelines intended for the user,									
(3) service information, and									
(4) recommended spare parts list;									
m. Repair procedures, parts lists, and schematic electrical and hydraulic drawings, or a statement that these items are available on request;									
n. Conditions and procedures for storage;									
o. Warnings and precautions about known adverse effects from improper installation or use;									
p. A statement that information about the limits of performance specifications is available on request;									
q. A list of the monitors that are included with the system and a warning that operation of the system without these monitors is hazardous;									

QUESTIONS	YES	NO	N/A	YES	NO	N/A	YES	NO	N/A
	TYPE A			TYPE B			TYPE C		
r. Procedures to minimize bacterial growth in the fluid pathway;									
s. A warning that the monitor of the dialysate concentration should be checked with an independent method;									
t. The accuracy and sensitivity of monitors;									
u. The preset monitor limits;									
v. The need for isolation of blood circuit pressure monitors from the blood to prevent contamination of the monitor with microorganisms and a recommended means of accomplishing this;									
w. The time delay from the occurrence of a blood leak at the rate of 0.35 ml/min at a hematocrit of 25 (0.25), to the initiation of a blood leak alarm (over the range of dialysate flow rates);									
x. Whether dialysate pressure monitors measure inlet, outlet, or mean pressure, typical line pressure drop at a standard flow rate; and a statement that the actual pressure at the dialyzer may differ from that indicated by the monitor, depending upon the relative height difference between the dialyzer and the monitor transducer and on flow in the dialysate lines;									
y. Whether transmembrane pressure monitors, if provided, measure inlet, outlet, or mean pressure of the inlet and outlet on the blood and/or dialysate sides of the dialyzer;									
z. In the case of batch systems not equipped with concentration monitors, a warning that the dialysate concentration should be checked before beginning dialysis;									

QUESTIONS	YES	NO	N/A	YES	NO	N/A	YES	NO	N/A
	TYPE A			TYPE B			TYPE C		
aa. Generic identification of materials of construction in contact with reagents for dialysate, final dialysate, or otherwise in the fluid pathway;									
bb. Where air embolism protection is a feature of the device: (1) a statement of the sensitivity of the device to air and foam,									
(2) a statement that details of the test method are available on request,									
(3) sensitivity specified for both air in blood and air in saline,									
(4) the sensitivity specification states the maximum undetected flow rate of air;									
cc. Alarm adjustment strategy to be used by the operator to maximize the probability of detecting a blood leak in the extracorporeal circuit; and									
dd. If appropriate, a warning that hemolysis may occur in the dialyzer in the event of certain malfunctions, such as excess temperature or hypotonic dialysate, and that hemolyzed blood should not be returned to the patient.									

Comments:

QUESTIONS	YES	NO	N/A	YES	NO	N/A	COMMENTS
	TYPE A			TYPE B			
4. Does the label on the concentrate container provide the following minimum information: (AAMI 3.1.3)							
a. Name and address of the manufacturer;							
b. Date of manufacture;							
c. Identifying lot number;							
d. Composition, including the metric weight of each ingredient;							
e. For batch systems, the volumes of dialysis concentrate and water that shall be mixed;							
f. For proportioning systems, the ratio of dialysis concentrate and water that shall be mixed;							
g. Composition of the diluted solution, including: (1) nominal measured conductivity in millisiemens (ms) or millimhos per centimeter (mmhos/cm) at 25°C							
(2) concentration of each electrolyte in the diluted solution in milliequivalents per liter (meq/l)							
(3) concentration of nonelectrolytes in the diluted solution in milligrams per deciliter (mg/dl)							
h. Fill volume of the container;							
i. Trade name of the product.							
5. Aqueous Concentrate. Label includes: (AAMI 3.1.1.1)							
a. manufacturer's recommended storage temperature range;							
b. instructions to mix thoroughly prior to use;							
c. instructions for determining whether precipitate has been adequately reconstituted;							
d. instructions not to use damaged containers;							

QUESTIONS	YES	NO	N/A	YES	NO	N/A	COMMENTS
	TYPE A			TYPE B			
e. if bicarbonate is used, a warning noting that bacterial growth may occur in concentrated bicarbonate solutions and storage time should be determined by the user; and							
f. means for user to readily distinguish between solutions when more than one are used together to produce dialysate.							
6. Dry Concentrate. The label includes: (AAMI 3.1.1.2)							
a. instructions to avoid excessive temperature; and							
b. keep container tightly sealed until use.							
Extracoporeal Blood Circuit							
7. Blood Pump. Do instructions for use include:							
a. details of the calibration technique used by the manufacturers to convert speed to flow rate?							
b. special features of the pump?							
c. tubing characteristics necessary for safe and effective operation?							
d. procedure and appropriate schedules for calibrating and testing pump?							
e. procedure for discontinuing use?							
8. Are warnings and contra-indications concerning improper installation or use provided?							

Comments:

QUESTIONS	YES	NO	N/A	YES	NO	N/A	YES	NO	N/A
Dialyzers	TYPE A			TYPE B			TYPE C		
*9. Do instructions for use include:									
a. all materials used in the construction of the dialyzers that contact blood or dialysate?									
b. set-up checklist, including unpacking and inspecting?									
c. warnings and contraindications concerning improper installation or use?									
d. connections to other equipment?									
e. initiation of use; preuse testing if appropriate?									
f. priming?									
g. operational adjustments?									
h. procedures to be followed if the dialyzer fails?									
i. reuse procedures?									
j. discontinuation of use?									
k. shut-down?									
l. clean-up and sterilization procedures?									
m. procedures for storage between uses?									
	TYPE D			TYPE E			TYPE F		
*10. Do instructions for use include:									
a. all materials used in the construction of the dialyzers that contact blood or dialysate?									
b. set-up checklist, including unpacking and inspecting?									
c. warnings and contraindications concerning improper installation or use?									
d. connections to other equipment?									
e. initiation of use; preuse testing if appropriate?									
f. priming?									
g. operational adjustments?									
h. procedures to be followed if the dialyzer fails?									
i. reuse procedures?									
j. discontinuation of use?									
k. shut-down?									
l. clean-up and sterilization procedures?									
m. procedures for storage between uses?									

APPENDIX C

TABLE 1
FACILITIES SURVEYED

Dialysis Unit	Location
Biomed Applications of Boston*	Dorchester
Brockton Dialysis Center*	Brockton
Cape Cod Artificial Kidney*	Yarmouth
The Kidney Center*	Boston
Southeastern Mass. Dialysis*	New Bedford
Western Mass. Kidney Center*	Springfield
BioMed Application of Framingham*	Framingham
Bay State Medical Center	Springfield
Berkshire Medical Center	Pittsfield
Beth Israel Hospital	Boston
Beverly Hospital	Beverly
Brigham and Women's Hospital	Boston
Children's Hospital	Boston
Franklin Medical Center	Greenfield
Mary and Arthur Clapham Hospital	Burlington
Mass. General Hospital	Boston
Memorial Hospital	Worcester
Nantucket Cottage	Nantucket
New England Deaconess	Boston
New England Medical Center	Boston
University Hospital	Boston
St. Elizabeth's Hospital	Boston
Merrimack Dialysis Unit	Merrimack

* Free-standing dialysis units.

TABLE 2

Hemodialysis Water Quality - Chemical Contaminant Levels*

Contaminant	Suggested Maximum Level (mg/l)
Calcium	2
Magnesium	4
Sodium**	70
Potassium	8
Fluoride	0.2
Chloride	0.5
Chloramines	0.1
Nitrate (N)	2
Sulfate	100
Copper, Barium, Zinc	0.1 each
Aluminum	0.01
Arsenic, lead, Silver	0.005 each
Cadmium	0.001
Chromium	0.014
Selenium	0.09
Mercury	0.0002

*A.A.M.I. National Standard recommendations

**230 mg/l where sodium concentration in concentrate has been reduced to compensate for excess sodium in the water, as long as conductivity of water is continously monitored.

TABLE 3

WATER TREATMENT - RESPONSE TO QUESTIONS REGARDING

OPERATIONS, MONITORING AND ALARM

NUMBER	QUESTION	RESPONSE YES	NO
14a	Equipment Disinfected	21	1
16a	Conductivity Alarm Tested	18	4
18a	Warning & Alarm system calibrated	12	10
21	Water ph monitored	21	1
23a	Regenerated or Recon-stitated devices disin-fected	17	5
23b	Processes employed to ensure no intermixing	20	2
25a	Analyses performed to determine quality of water chlorine	19	3
	Chlorine Maximum level at 0.5 mg/l	21	1
	Chloramines	20	2
	Aluminum maximum level at 0.01	19	3
27	Deionization effluent monitored	20	2
28a	Reverse osmosis system monitored	18	4
28b	Conductivity of feed and passage water monitored	17	5
31a	Water purification subsystem disinfected	18	4

TABLE 4

WATER TREATMENT - RESPONSES TO QUESTIONS REGARDING

MALFUNCTIONS AND DESIGN ERRORS

NUMBER	QUESTIONS	RESPONSE	
		YES	NO
16	Alarm on Conductivity Monitors	17	5
19a	Alarm Failures	2	20
30	Opaque Housing for Sediment Filters	19	3
33a	Safe Configuration in the Event Control Limits are Exceeded	17	5
33e	Audible Alarms at least 70 decibels at 3 Meters	14	7
34c	Electrical Receptables Shielded from Liquid Spills	19	3
34e	Audible Alarm for Main Failure	12	10

TABLE 5

WATER TREATMENT - INSUFFICIENT PROVISION OF INFORMATION BY THE MANUFACTURER

NUMBER	QUESTIONS	INFORMATION PROVIDED	
		YES	NO
1a	Requirements for Utilities	10	1
1e	Environmental Conditions	9	2
1f	Discription of Equipment	10	1
1g	Safety Features and Warnings	8	3
1h	Incompatible Chemicals	7	4
1l	Water Specifications	9	2
1o	Initial Adjustment of Alarms, and Monitors	9	2
1q	Alarm Procedures	8	3
1t	Clean-up and Steriliza-tion Procedures	9	2
1v	Degree of Removal of Chemical Contaminants after Water Purification	9	2
1w	Water Quality Issues	5	6
1x	Contaminated Carbon Warning	8	3

NUMBER	QUESTIONS	INFORMATION PROVIDED	
		YES	NO
1y	Warning on Responsibility for the Selection of Water Equipment and Water Testing	5	6
1aa	Description of Method to Avoid Intermixing of Devices from Potable and Nonpotable Water User	7	4
1bb	Information on Incompatible Chemicals	6	5
1cc	Information on online Monitors of Water Quality	8	3
1dd	Identification of Mechanism Preventing Excessive Contaminants During Regeneration	8	3
1ff	Warnings of Improper Installation or Use	8	3

TABLE 6

WATER TREATMENT - RESPONSES TO QUESTIONS REGARDING EQUIPMENT MARKINGS AND OPERATING INSTRUCTIONS

NUMBER	QUESTIONS	RESPONSE YES	NO
3e	Warnings on Substances to be Removed Before Using	9	13
3f	Identification of Fittings	13	9
5	Instructions for use Provided	17	5
6	Operating Instructions Satisfactory	21	1
7	Maintenance Instructions Provided	21	1
8	Maintenance Instructions Satisfactory	21	1
9	Warnings on Improper Installation and Use	17	5

TABLE 7

WATER TREATMENT - RESPONSES TO QUESTIONS REGARDING MISCELLANEOUS PROBLEMS

NUMBER	QUESTIONS	RESPONSE YES	NO
12a	Contact with Water Department when Chemical Composition of Water Changed	11	11
12b	Contact with Water Department when Source of Water Changed	11	11
27c	Nitrosamines Produced	1	21

TABLE 8

DIALYSATE DELIVERY SYSTEM - RESPONSES TO QUESTIONS REGARDING OPERATIONS, MONITORING AND ALARMS AND MALFUNCTIONS AND DESIGN ERROR

NUMBER	QUESTIONS	RESPONSE YES	NO
1. Operations, Monitors, Alarms			
55	Dialysate Circuit Pressure Monitored	19	3
2. Malfunctions and Design Errors			
53	Alarm Malfunction	4	18
56	Dialysate Circuit Pressure	18	4

TABLE 9

DIALYSATE DELIVERY SYSTEM - INSUFFICIENT PROVISION Of INFORMATION BY THE MANUFACTURER

NUMBER	QUESTIONS	INFORMATION PROVIDED	
		YES	NO
3e	Environmental Conditions	6	4
3g	Safety Features	9	1
3h	Incompatible Chemicals	9	1
3i(5)	Procedures for Testing of Monitors, Alarms and Controls	7	3
3j(3)	Instructions for Operational Adjustments	9	1
3j(4)	Instructions for Operation and Meaning of Alarms	9	1
3k	Procedures for Discontinuing Use	9	1
3o	Warnings of Effects of Improper Installation and Use	5	5
3s	Warning that Dialysate Concentration Monitor Should be Checked Independently	1	9
3x	Dialysate Pressure Monitor Information	4	6

NUMBER	QUESTIONS	INFORMATION PROVIDED	
		YES	NO
3y	Transmembrane Pressure	4	6
3z	Warning to Check Dialysate Concentration before Dialysis	8	2
3bb(1)	Statement of Sensitivity to Air and Foam	3	7
3bb(3)	Statement of Specified Sensitivity for Air in Blood and Saline	0	10
3bb(4)	Specification of Maximum Undetected Air Flow Rate	0	10
3cc	Alarm Adjustment Strategy Detecting of Blood Leak	4	6
3dd	Warning that Hemolysis May Occur from Certain Malfunctions	1	9

TABLE 10

DIALYSATE DELIVERY SYSTEM - RESPONSES TO QUESTIONS

REGARDING MISCELLANEOUS PROBLEMS

NUMBER	QUESTIONS	RESPONSE	
		YES	NO
42	Modifications to Equipment	3	19
47	Problems with Concentrate	1	21

TABLE 11

EXTRACORPOREAL BLOOD - RESPONSES TO QUESTIONS

REGARDING OPERATIONS, MONITORING, ALARMS

NUMBER	QUESTIONS	RESPONSE	
		YES	NO
66a	Sensitivity of Air/Foam Detector Measured	15	7
67a	IV Fluid Administered After Air/Foam Detector	17	5
68	Glass Bottles Used to Administer IV Fluids	20	2

TABLE 12

RESPONSES TO FURTHER QUESTIONS REGARDING THE EXTRACORPOREAL BLOOD CIRCUIT

NUMBER	QUESTIONS	RESPONSE	
		YES	NO
1. Malfunctions or Design Errors			
65f	Audible and Visual Alarms to Indicate that Air Detector Not Activated	19	3
66c	Problems with Air/Foam Detectors	4	18
89d	Electrical Receptables Shielded from Liquid Spills	20	8
2. Insufficient Information or Training			
7a	Details of Calibrabration Technique to Convert Speed to Flow Rate	0	3
8	Warning on Improper Installation and Use	2	1
3. Equipment Markings and Operator Instructions			
65b	Manufacturers' Guidelines Adequate	21	1

TABLE 13

DIALYZERS - RESPONSES TO QUESTIONS REGARDING

OPERATIONS, MONITORING AND ALARMS

NUMBER	QUESTIONS	RESPONSE	
		YES	NO
102	Practice Reuse	11	11
108a(1)	Quality Control for Cell Volume	20	2
108a(3)	Quality Control or Clearence Measurements	18	4

TABLE 14

DIALYZERS - INSUFFICIENT PROVISION OF INFORMATION BY THE MANUFACTURER

NUMBER	QUESTIONS	INFORMATION PROVIDED	
		YES	NO
9a	Construction Materials that Contact Blood or Dialysate	7	4
9b	Set-up Check list	5	6
9h	Procedures for Dialyzer Failure	7	4
9i	Reuse Procedures	0	11
9j	Discontinuation of Use	6	5
9k	Shut-down Procedures	5	6
9l	Clean-up and Sterilization Procedures	4	7

TABLE 15

PROBLEMS, SATISFACTION AND HYPERSENSITIVITY AND PYROGENIC REACTIONS FOUND IN 11 FACILITIES PERFORMING REUSE

NUMBER	QUESTIONS	RESPONSE		DIALYZER		
		YES	NO	NEW	REUSED	BOTH
112	Reuse Problems	1*	10	-	-	-
113	Satisfied with Reuse	11	0	-	-	-
114	Hypensensitity Reactions	5	6	3	0	2
115	Pyogenic Reactions	2	9	0	0	1**

*. One facility reported increased Thrombosis with dialyzer reuse

** One facility did not report whether pyrogenic reactions were with new or reused dialyzers.

TABLE 16

DIALYZER - RESPONSES TO QUESTIONS REGARDING

MISCELLANEOUS PROBLEMS

NUMBER	QUESTIONS	RESPONSE	
		YES	NO
98	Blood Membrane Interactions	4	18
114	Hypersensitivity Reactions	7	15
115	Pyrogenic Reactions	3	19
97	Problems with Dialyzer Packing	1	21